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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/621,254	DOW ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,19,31-45,47,50-52,55-68,85-87,112-121 and 151-157* is/are pending in the application.

4a) Of the above claim(s) *8,19 and 157* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10,12-121 and 151-156* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group X in the reply filed on 2/5/2007 is acknowledged. The traversal is on the ground(s) that the restriction is improper because it is an improper separation of the genus into species without recognition of the genus claims. This is not found persuasive because the restriction acknowledged the presence of generic claims by listing those claims as linking claims. Applicants are correct in their understanding that if all species claims are found allowable, then the linking claims will be considered allowable. Applicants are incorrect in equating the term "linking" with "not generic". When a restriction is based on a linking claims analysis, a set of species claims is examined along with any linking claims, which are examined under 35 USC 112, first and second paragraphs to the full extent of their scope, and any prior art that is found that is generic is also discussed. Therefore, applicants' concerns that the generic concepts will not be examined are unfounded. Applicants' remarks with respect to the election of species requirement are noted, and the examiner acknowledges that the requirement for an election of species is for purposes of facilitating search and examination, and the search will be extended to the next species to allow for consideration of the generic claim encompassing the species.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-10, 19, 31-45, 47, 50-52, 55-68, 85-87, 112-121, and 151-157 are pending.

Claims 8, 19, and 157 drawn to non-elected inventions, are withdrawn from consideration. Claim 8 is drawn to a method that includes "down regulating an immune

response", which does not appear to be a step that is contemplated in the treatment of a subject with cancer.

Claims 1-7, 9, 10, 31-45, 47, 50-52, 55-68, 85-87, 12-121 and 151-156 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6, 7, 9, 31-45, 47, 50-52, 55-68, 112-121, 151, 152 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because it is not clear if the phrase "further comprising modulating an immune response in said subject" is a reference to the effect of performing the method of claim 1, or if this refers to an additional active step. Because administering a composition comprising a ligand for a pattern recognition receptor modulates an immune response, the claim would be clear if it contained a step of administering another product or composition

Claims 9 and 112 are indefinite because of the phrase "in a subject disposed of cancer". Does this phrase mean that the subject is disposed to cancer, i.e. has a predisposition for the development of a cancer? Or does this phrase mean that the subject once had a cancer, which has been removed (disposed of)?

Claim 112 is further indefinite because in the preamble the claim reads "treating a subject with cancer", whereas in the body of the claim, the claim reads "wherein said method elicits a response in a subject disposed of cancer".

Claim 31 is indefinite because of the phrase "is capable of inducing an immune response in a subject". The use of the phrase "capable of" renders the claim indefinite because phrase "capable of" is not a positive recitation of the activity of inducing an immune response, but instead is only an indication of what the composition may be capable of.

Claim 38 is indefinite because of the phrase "any combination of liposomes". It is not clear whether this refers to liposomes made of different lipids, or comprising different drugs, etc... There is no antecedent basis for the concept of different types of liposomes in claim 31, from which claim 38 depends.

Claim 66 is indefinite because the claim is dependent from claim 31, which is a claim to a method, whereas the phrase in claim 66 of "further comprising a steroid backbone" is limitation that would be appropriate for a claim to a composition or a product.

Claim 67 is indefinite because the claim is dependent from claim 60, which is a claim to a method, whereas the phrase in claim 67 of "further comprising a DNA condensing agent" is limitation that would be appropriate for a claim to a composition or a product.

Claim 151 is indefinite because of the phrase "wherein a lignd for a pattern recognition molecule receptor comprises a ligand for an pattern recognition receptor". It is not clear what the difference is between "pattern recognition molecule receptor" and "pattern recognition receptor".

Claim 152 is indefinite because the phrase "the therapy" lacks antecedent basis in claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 9, 10, 112-121 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating a subject having cancer, does not reasonably provide enablement for methods of preventing cancer in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The basis for this rejection is that the specification fails to enable one of skill in the art to use the claimed compositions as prophylactic or therapeutic cancer vaccines for the intended use of preventing cancer. The claims are interpreted as reading on methods for the prevention of cancer because the claims contain the recitation that the subject is disposed of cancer, which appears to mean that the subject has a predisposition to cancer.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

On page 10 of the specification, the specification teaches that the compositions of the invention may be used to prevent or treat primary lung cancers and pulmonary metastatic disease. Therefore, the compositions of the invention may be used to prevent the development of cancer or to treat a patient afflicted with a cancer. The specification provides no working embodiments demonstrating prevention of cancer. Therefore, the teachings of the specification are prophetic.

For the claimed methods that relate to the prevention of cancer, there is no guidance in the specification for determining the appropriate time prior to the development of tumors to begin the therapy or for identifying patients at risk for developing those tumors. Further, Chamberlain (Chamberlain, R.S. et al. Expert Opinion on Pharmacotherapy, 1(4): 603-614, 2000) teaches that while vaccines are classically administered prophylactically to evoke an immune response capable of providing protection against infection by the same or similar pathogens for the treatment of infectious diseases, this has not been the approach in the field of cancer immunotherapy. In the treatment of infectious diseases, there is an a priori inoculation with a pathogen resulting in protection on subsequent encounter. However, cancer is not an infectious process. Cancer cells express a limitless number of antigens and a priori knowledge of whom in the population is at risk for which cancer is lacking (see page 604, 1st column, first full paragraph). The specification provides insufficient guidance in regard to the issues raised above and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed methods with a reasonable expectation of success. In view of the above, one of skill

in the art would be forced into undue experimentation to use the claimed compositions as preventative vaccines.

Thus, in view of the contemporary knowledge in the art of the general lack of successful applications of vaccines for the prevention of human cancer as discussed above, coupled with the lack of working examples in the specification that relate to the prevention of cancer, one of skill in the art would be forced into undue experimentation in order to use the invention for the prevention of cancer in subjects disposed of cancer.

5. Claims 1-7, 31-45, 47, 50-52, 55-68, 85, 151-156 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis of this rejection is that the amendment filed 2/5/2007 introduces new matter into the specification as originally filed because the claims have been amended to recite methods for treating any individual comprising administering a ligand for a pattern recognition receptor and exposing the subject to radiation, whereas the originally filed specification and claims referred to the use of radiation only for the treatment of subjects with cancer. This amendment constitutes a broadening of the scope of the claims to a genus of methods that was not originally contemplated.

As the claimed methods are currently recited, they read on methods of treating subjects having any type of disease, where the steps of the method comprising administering a composition comprising a ligand for pattern recognition receptor and exposing the subject to

radiation. The amendment does not point to specific passages in the specification for support for the amendment filed 2/5/2007. Additionally, a review of the specification, shows that methods comprising a step of exposing the subject to radiation were only contemplated for subjects having cancer. Therefore, the new claims are broader in scope and include methods where the steps of administering a ligand for a pattern recognition receptor and exposing the subject to radiation are to be used for the treatment of any disease. This broadening of scope constitutes new matter, and one of skill in the art would not find that applicants were in possession of the claimed methods at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-7, 9, 10, 31-33, 41, 52, 61, 63, 64, 85-87, 112-117, 118, 119, 121, 151-155 are rejected under 35 U.S.C. 102(b) as being anticipated by Milas (Milas, L., Develop. biol. Standard., 38: 301-306, 1978) as evidenced by Hacker (Hacker, G. et al. Immunology, 105: 245-251, 2002, March).

The claims are drawn to methods comprising the administration to a subject a composition comprising at least one ligand for a pattern recognition receptor and a delivery vehicle and exposing the subject to radiation. The specification teaches that the delivery vehicle may be a liposome, and also teaches pharmaceutically acceptable excipients (see page 8). Therefore, the term "delivery vehicle" is interpreted broadly as anything that is used in the process of delivering the composition comprising the ligand, such as an excipient. The ligand for a pattern recognition receptor may be a ligand for a Toll-like receptor such as TLR-9, or may be a ligand for an endocytic pattern recognition receptor. The phrase "endocytic pattern recognition receptor" is interpreted to mean that the pattern recognition receptor may be endocytosed after binding with its ligand or is a receptor associated with an endosome. The method may further comprise modulating an immune response, which is interpreted to mean that in addition to the steps of administering the ligand and delivery vehicle and exposing the subject to radiation, that another compound is administered that has an effect on the immune system of the subject. The subject may have cancer. The phrase "complexed to or within the delivery vehicle" is interpreted to mean that the ligand may be mixed with the delivery vehicle. Claims 115-117 contain limitations concerning the order of introducing the therapy (introduced first, introduced last, introduced concurrently).

Milas teaches a method that comprises intravenous administration of formalin-killed C. parvum diluted in solution A (8.0 NaCl, 0.4 g KCl, 1.0 g glucose and 0.35 g $NaHCO_3$ in 1 liter H_2O) and γ-irradiation in mice bearing mammary tumors (see abstract and page 302 1st and 2nd paragraph). Therefore, Milas teaches the method steps of administering a composition comprising a ligand (C. parvum) with a delivery vehicle (solution A, which is non-liposomal)

and also administering radiation. Milas teaches a step of further administering vitamin A (see page 303). Milas performs the method where the radiation therapy is administered before the C. parvum injection (reads on introduced first), where the radiation therapy is administered multiple times during the period when C. parvum is administered (reads on administered concurrently) and where the radiation therapy is administered after C. parvum (reads on administered last). Hacker provides evidence that bacterial DNA is pathogen-associated molecular pattern (PAMP) that appears to require TLR-9 (which appears to be a receptor that is associated with endosomes) expression in immune cells, or of the catalytic subunit of the DNA-dependent protein kinase (DNA-PKcs, which appears to be a receptor that is endocytosed) (see abstract, and page 248-249, and Figure 1). Therefore, Milas teaches a method comprising the administration of a composition comprising a pattern recognition receptor ligand and a delivery vehicle and exposing the subject to radiation, where the composition is one that is capable of inducing an immune response in a subject.

7. Claims 1-7, 9, 10, 31-34, 41-45, 52, 61, 64, 65, 85-87, 112, 113, 118, 119-121, 151, and 156 rejected under 35 U.S.C. 102(e) as being anticipated by Raz (US 6,534,062; issued Mar. 18, 2003; effective filing date is July 5, 2000).

Raz teaches a method comprising the administration of an immunostimulatory nucleic acid and subjecting the subject to radiation, because Raz teaches that the composition comprising the immunostimulatory nucleic acid may be administered to a cancer patient that has undergone radiation therapy (see claim 8, column 46). Raz teaches delivery vehicles that are liposomal and non-liposomal (see column 24, line 61 – column 26, line 42). Raz teaches combination therapy,

which includes various examples of chemotherapy (see column 26, line 60 to column 27, line 39). Thus, Raz teaches a method that is the same as that claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-5, 31-37, 39, 40, 43-44, 61, 64, 65, 85, 112, 118, 120, 151, and 156 are rejected under 35 U.S.C. 103(a) as being obvious over Dow (US 6,639,086; issued Feb. 17, 2004; effective filing date, June 25, 1998) in view of Milas (supra).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Dow teaches methods for treating cancer comprising the administration of immunostimulatory nucleic acids complexed with liposomes, such as the liposomes as recited in claims 34-37 (see column 6, lines 41-58). Dow teaches a method that can elicit a systemic, anti-tumor immune response in a mammal that results in an increase in effector cell activity and particularly natural killer cell activity and an increased production if interferon gamma (see

column 3, lines 8-25). Dow teaches that the nucleic acid may be any nucleic acid, coding or non-coding, and not necessarily operatively linked to a transcription control sequence (see column 13, lines 14-29). Dow also teaches the use of a recombinant nucleic acid (reads on synthetic DNA) (see column 13, lines 34-35). Dow teaches administering the compositions comprising immunostimulatory nucleic acids complexed with liposomes to cancer patients, but fails to explicitly teach administering to cancer patients that are also receiving radiation therapy. Dow fails to teach methods comprising the further administration of radiation therapy.

However, the method of Dow is a method of treating cancer by stimulating the immune system of the subject to attack the subject's cancer, and Milas teaches that in cases where there is a large tumor burden, that immunotherapeutic methods may not be sufficient. Thus, Milas teaches combining an immunotherapeutic method with radiation therapy to increase the effectiveness of an immunotherapeutic method. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the methods of Dow to stimulate the immune system of a cancer patient for the purpose of treating the cancer and to modify the method of Dow by combining Dow's method with radiation therapy as suggested by Milas. One would have been motivated by the teachings of Milas that methods of treating cancer by immunotherapy may be enhanced by combining with radiation therapy.

9. Claims 1-7, 9, 10, 31-33, 41, 42, 52, 61, 64, 65, 85-87,112, 118, 119, 121, 151, and 156 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis (US 6,406,705; issued June 18, 2002; effective filing date June 3, 1999).

Davis teaches a method of treating cancer comprising administering a CpG dinucleotide and a non-nucleic acid adjuvant (see column 8, lines 56-64 and column 10, lines 23-40; column 10, line 56- column 15, line 35). Davis fails to teach a method combining the immunotherapeutic method of administering CpG dinucleotides with radiation therapy. However, Milas teaches that in cases where there is a large tumor burden, that immunotherapeutic methods may not be sufficient. Thus, Milas teaches combining an immunotherapeutic method with radiation therapy to increase the effectiveness of an immunotherapeutic method. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the methods of Davis to stimulate the immune system of a cancer patient for the purpose of treating the cancer and to modify the method of Davis by combining Davis' method with radiation therapy as suggested by Milas. One would have been motivated by the teachings of Milas that methods of treating cancer by immunotherapy may be enhanced by combining with radiation therapy.

10. Claims 1, 31, 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raz (supra) in view of Maes (US 3,725,545; issued Apr. 3, 1973).

Within the scope of claims 1, 31 and 60-62 are methods where the ligand is an oligonucleotide that comprises at least one of poly I:C or related ply I:C oligonucleotides.

Raz fails to explicitly teach immunostimulatory nucleic acids that are poly I:C oligonucleotides or related poly I:C oligonucleotides. However, Maes teaches methods for potentiating antibody producing ability of nucleic acid containing preparations where the nucleic acid is polyinosinic acid, or poly I:C (see column 6, lines 26-62). Therefore, it would have been

prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the nucleic acids of Maes in the method of Raz, because Maes teaches polyinosinic acid are immunostimulatory oligonuceotides (have antibody producing ability). One would have been motivated to use the method of Raz with the method of Maes because both are methods directed to increasing the functionality of the immune system with respect to polynucleotides.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
May 14, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER